

CMS Issues New Conditions for Coverage for Ambulatory Surgical Centers



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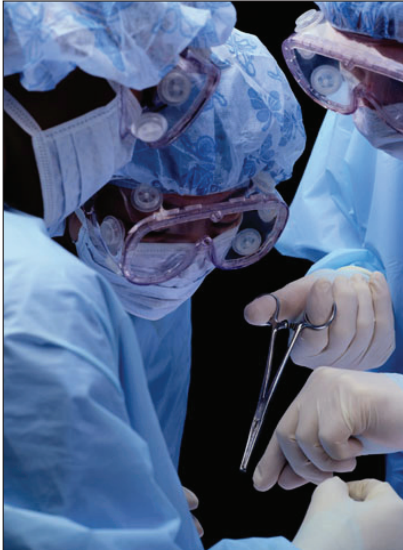
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The Centers for Medicare and Medicaid Services (CMS), on Aug. 31, 2007, released a proposed rule that would revise the conditions for coverage for ambulatory surgical centers (ASCs). See 72 Fed. Reg. 50,470 (proposed Aug. 31, 2007) (to be codified at 42 C.F.R. pt. 416). The proposed rule includes the most significant revisions to the conditions for coverage in more than two decades. According to CMS, these changes “reflect contemporary standards of practice in the ASC community, as well as recommendations from the HHS Inspector General.”

Specifically, the proposed rule would revise three existing conditions for coverage: (1) governing body and management; (2) evaluation of quality, which would be renamed quality assessment and performance improvement; and (3) laboratory and radiology services. The proposed rule would also add three new conditions for coverage: (1) patient rights; (2) infection control; and (3) patient admission, assessment and discharge.



Key Changes

All in all, the additional conditions for coverage would increase information collection requirements and other administrative obligations for ASCs. That stated, the most significant business impact of the proposed rule could arise from two key provisions: (1) the addition of a newly codified definition for “overnight stay” in the context of ASCs; and (2) a statement and a new rule applicable to patient transfers.

A. New Definition for Overnight Stay

The existing conditions for coverage define an ASC as “any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.” 42 C.F.R. § 416.2. The proposed conditions for coverage would add a new and clearer overnight stay element to the definition of ASC.

On the definition of ASC and the new overnight stay element, CMS stated:

Ambulatory surgical center or ASC would mean any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring an overnight stay following the surgical services, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

The overnight stay definition would read as follows:

Overnight stay, for purposes of the ASC CfCs, would mean the patient’s recovery requires active monitoring by qualified medical personnel, regardless of whether it is provided in the ASC, beyond 11:59 p.m. of the day on which the surgical procedure was performed.

To provide further clarification on the overnight stay definition, we are proposing to use the 11:59 p.m. threshold as the standard for determining a patient’s status when receiving services in an ASC facility. In the Medicare cost reporting manual (Provider Reimbursement Manual, Part 1, Section 2205 (Medicare Patient Days, page 22–16)), we have defined a hospital inpatient day as beginning at midnight and ending 24 hours later. Consistent with this longstanding policy, we would codify in regulations that any patient whose recovery requires active monitoring by qualified personnel beyond 11:59 p.m. of the day on which the surgical procedure

was performed, is a patient who may require hospitalization or more intensive care. Accordingly, ASCs that are Medicare certified may not keep patients beyond 11:59 p.m. of the day on which the surgical procedure was performed.

The potential codification of this new definition raises two important issues. First, the proposed rule could impact the ability of surgical centers to see non-Medicare patients that stay past 11:59 p.m. The existing conditions for coverage do not include an overnight stay element in the definition of ASC. The conditions merely limit reimbursement to surgical procedures “generally requiring a post-operative recovery room or short-term (not overnight) convalescent room” without further defining the term “overnight.” 42 C.F.R. § 416.65(a)(3). CMS contends that the proposed definition is consistent with a “longstanding policy,” described in the Medicare cost of reporting manual, of defining “a hospital inpatient day as beginning at midnight and ending 24 hours later.”

B. Patient Transfers

A second issue relates to the requirement for transfer agreements between surgical centers and local hospitals. Here, CMS appears to recognize the frequent political and competitive issues between local surgical centers and hospitals that often make it difficult for an ASC to obtain a transfer agreement with a local hospital. Notwithstanding this issue, the comments state that the ASC must transfer the patient to the most appropriate local hospital, regardless of business at those hospitals. Specifically, CMS states:

. . . Regardless of any business issues that may arise between ASCs and their local hospital, the ASC would be required to transfer patients to the nearest, most appropriate local hospital, since this would affect patient health. Any transfers that do not meet the requirements of proposed § 416.41(b)(1) and (2) would be determined out of compliance with Medicare regulations.

Currently, the conditions for coverage require only “an effective procedure for the immediate transfer to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC.” 42 C.F.R. § 416.41. The proposed rule could pose challenges for ASCs by potentially placing ASCs in a difficult bargaining position with hospitals.

Remaining Changes

The remaining changes to the conditions for coverage provide for additional controls, some of which are bureaucratic. Commentary issued with the conditions of coverage provides insight into the agency’s rationale behind the proposed changes.

A. Statement and Rule on Patient Rights

The proposed rule adds a new condition not previously included in prior rules requiring ASCs to notify patients of their rights, and providing for exercise of such rights. Specifically, the proposed rule addresses:

- Notice (orally, in writing and on the wall) of patient rights, including the name and address of the application state agency to which patients can direct complaints (and communications must be given clearly in the patient's own language through an English-speaking representative of the family or a translator)

- Disclosure of physician financial interests in the ASC orally and in writing prior to the first visit to the ASC
- Policies relating to advance directives and the provision of information relating to advance directive options under state law to patients
- Grievance process pursuant to which patients can address patient rights issues at the facility level including a time frame for response and follow-up that patients can expect
- Protection of patient dignity and property (including a specific example described in the commentary, which includes providing space for patients to disrobe privately and to await surgery separate from clothed family members and others)
- Confidentiality of clinical records, including compliance with existing HIPAA rules and the requirement that clinical records cannot be disclosed or used without patient written consent ASCs to give patients information about federal and state laws pertaining to these issues



Many of these new patient rights requirements have been implemented and routinely followed by ASCs. However, the new requirements will necessitate additional time and resources during admission and consultation stages. In particular, the advance directives policies and explanation will require the ASC to be well-versed in advance directives rules in its state, and to be able either to answer questions relating to advance directives or willing to reschedule procedures until any questions can be answered fully.

It is also unclear whether the new confidential records requirement will defer to certain exceptions set forth under HIPAA for the sharing of records with certain provider affiliates, during the course of an audit or extraordinary transaction, etc.

An excerpt from CMS commentary relating to the patient rights requirements is as follows:

The proposed standard at § 416.50(a), Notice of rights, would require the ASC to provide the patient or representative with verbal and written notice of the patient's rights in a language and manner the patient understands prior to furnishing care to the patient. The ASC would also be responsible for posting written notice of the patient rights in a place or places within the ASC where they are likely to be noticed by patients waiting for treatment. In addition, the notice of patient's rights must include the name, address and telephone number for a representative in the state agency to whom patients can report complaints about ASCs, and the CMS Web site for the Medicare Beneficiary Ombudsman (<http://www.cms.hhs.gov/center/ombudsman.asp>). (Section 923 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108-173)(MMA), mandated the creation of the Medicare Beneficiary Ombudsman at section 1808(c) of the act, to ensure that Medicare beneficiaries receive the information and help they need to understand their Medicare options and to apply their rights and protections. A Medicare Beneficiary Ombudsman Open Door Forum (ODF) has been established to provide an opportunity for beneficiaries, their caregivers and advocates to publicly interact with the Medicare Beneficiary Ombudsman to discuss issues and concerns regarding ways to improve the systems and processes within the Medicare program.

The ASC would also be responsible for meaningfully disclosing, if applicable, physician financial interests or ownership in the ASC facility in accordance with 42 CFR Part 420 (Program Integrity). The ASC must disclose the information in writing and furnish it to the patient prior to the first visit.

The disclosure of financial information should be such that patients and their representatives are able to clearly understand if the physician(s) who will be performing a procedure has a financial relationship with the ASC. It is incumbent on the ASC to be able to provide information that is not only technically correct, but also easily understood by persons not familiar with financial statements, legal documents or technical language. The ASC should be aware of the age and the cognitive abilities of its patients, and recognize that older patients may be confused when presented with a document that they cannot readily understand at first glance.

In § 416.50(a)(2), advance directives, the ASC would also be responsible for providing the patient or representative with verbal and written information concerning its policies on advance directives, including a description of applicable state law, and if requested, official state advance directive forms. In addition, the ASC would be required to inform the patient or representative of the patient's right to make informed decisions regarding their care, and to document in a prominent part of the patient's current medical record, whether or not the individual has executed an advance directive.

We believe that ASCs should be given flexibility to meet this requirement within the context of their unique patient populations. Differences exist among ASCs, therefore, ASCs should be allowed to determine the process they would use to comply with this proposed requirement. As a result, we are not establishing specific guidelines for implementation. We also believe that the ASC should be aware that questions may arise when informing patients of their rights, therefore, they should provide ample time for answering questions.

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We are also proposing a requirement titled "submission and investigation of grievances" at § 416.50(a)(3). This requirement would respond directly to the OIG report referenced earlier regarding management of patient grievances and any alleged violations against patients.

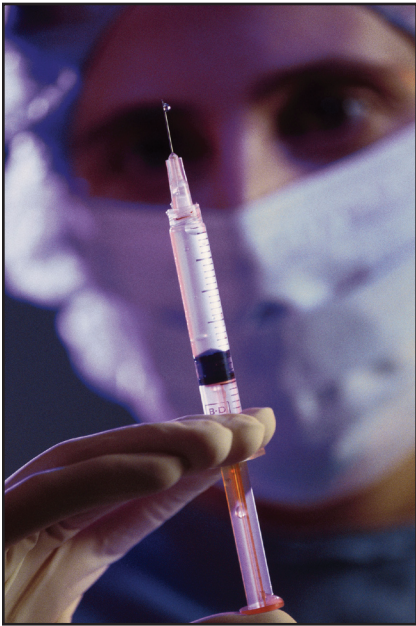
Grievance procedures are already in effect for numerous health care providers including ASCs. Similar to other internal procedures (for example, admission and discharge procedures, infection control procedures and others that are common to health care entities) the development and implementation of grievance procedures vary. Therefore, we have determined that it would be better to allow ASC to establish the specifics of a grievance system that may match its current one or needs rather than requiring that every ASC conform to a single grievance system.

We are proposing that the ASC would establish clearly explained procedures for documenting the existence, submission, investigation, and disposition of grievances presented to the ASC (either written or verbal) made by the patient or the patient's representative. ASCs would document all alleged violations related to and including, but not limited to, mistreatment, neglect, verbal, mental, sexual or physical abuse. If other allegations of mistreatment arise, such as theft of personal property, the ASC would document this allegation as well. The ASC would immediately report these allegations to a person in

authority in the ASC, the state, and local bodies having jurisdiction, and the state survey agency if warranted, to the extent that such reports are consistent with the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191) (HIPAA) and privacy provisions.

We are proposing that the grievance process specify time frames for review and response to the grievance. We are also proposing the ASC would be required to investigate, document, and respond to all grievances made by a patient or the patient's representative regarding treatment or care that is (or fails to be) furnished.

We are proposing that certain information be captured when documenting and responding to grievances. Proposed documentation should include such information as how the grievance was addressed, the steps taken during the investigation; written notice to the patient or representative of the ASC's decision (containing the name of an ASC contact person); the results of the grievance process; and the date the grievance process was completed, consistent with HIPAA and privacy requirements. ASCs could use different approaches to effectively meet this CfC. We would set forth the general elements that should be common to grievance processes across all ASCs, but we are not explicitly delineating strategies and policies that ASCs are required to use to comply with the requirement. Also, we would leave the degree of documentation to the discretion of the ASC.



...

We would propose at § 416.50(c), privacy and safety, that patients have the right to personal privacy and safety, to receive care in a safe setting, and to be free from all forms of abuse or harassment. For example, ASCs would be required to provide a private space in which patients could disrobe and wait until the surgical procedure begins, because we believe it is inappropriate for patients to be required to sit in a public waiting area while in a hospital gown with other fully clothed or similarly gowned patients, or be in a common patient area without the benefit of partitions. This right would also allow patients, for example, to identify and report dangerous or unsafe conditions, harassment or abusive behaviors within the ASC that the patient believes could negatively impact the services received at the ASC. We believe this requirement would act as an additional safeguard to patient health and safety.

The proposed "confidentiality of clinical records standard" at § 416.50(d) is designed to safeguard patients against unauthorized use of their clinical record. We would assure that the patient's right to confidentiality consistent with HIPAA standards, and that access to or release of patient information and clinical records is permitted only with written consent of the patient or representative or as authorized by law. We are proposing to add this requirement because patients have the right to communicate with health care providers in confidence and to have the confidentiality of their health care information protected. In addition, all ASCs would be required to comply with the HIPAA health information privacy rule at 45 CFR parts 160 and 164.

B. Governing Body and Management

With respect to governing body and management, CMS stated:

. . . We are proposing new language in the condition statement which would require the governing body to assume direct oversight and accountability for the QAPI program. The governing body would be responsible for ensuring that QAPI efforts, at a minimum, focus on identifying areas needing improvement, and that QAPI is implemented in accordance with § 416.43 of this part. Specific governing body QAPI responsibilities are detailed in the proposed QAPI requirement at § 416.43. By focusing on QAPI, ASC management would be expected to be better able to improve care being furnished to patients. We are also proposing that the governing body be responsible for creating and maintaining a disaster preparedness plan. In addition, we are proposing to retain the current requirement which provides that the ASC can contract for services with an outside resource. However, we propose to incorporate this language into a separate standard, located at § 416.41(a). The ASC's governing body would still be responsible for the services that are furnished.

. . .

. . . The ASC's governing body, as part of the ASC leadership component, would be responsible for maintaining a written disaster preparedness plan that would provide for the emergency care of patients in the event of fire, natural disaster, functional failure of equipment, or other unexpected events or circumstances that threaten the health and/or safety of its patients and staff members.

C. Quality Assessment of Performance Improvement

CMS also included a revised condition for quality assessment programs. Regarding this condition, CMS stated:

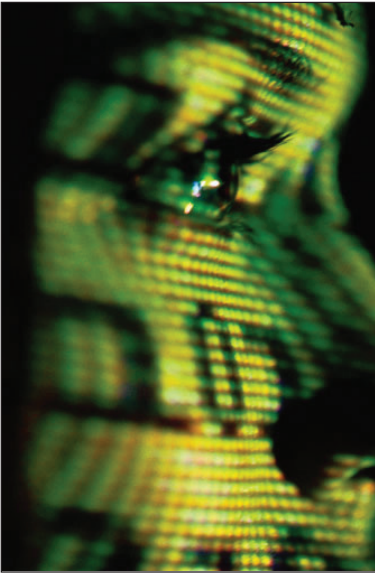
. . . To raise the performance expectations for ASCs seeking entrance into the Medicare program, as well as the expectations of those ASCs already participating in Medicare, we are proposing that each ASC also develop, implement, and maintain an effective QAPI program. Our aim is to support the development of patient-centered, outcome-oriented efforts that focus on patient health and safety. An ASC QAPI program would be designed to stimulate the ASC to constantly monitor and improve its own performance, and to be responsive to the needs, desires, and satisfaction levels of the patients it serves. . .

In proposed § 416.43(a), program scope, we are proposing that the ASC's QAPI program must include, but not be limited to, an ongoing program that demonstrates measurable improvement in patient health outcomes, and improves patient safety by using quality indicators or performance measures associated with improved health outcomes and with the identification of medical errors. . .

Monitoring care in an ASC can be challenging since the typical patient may be seen for only one visit. Therefore, it is critically important that an ASC's QAPI program identify high risk areas and areas of problematic care, and conduct follow-up analysis in a timely manner to identify specific areas in need of improvement. . .

. . .

At proposed § 416.43(c)(1), program activities, we propose to require that the ASC set priorities for its performance improvement activities that: (1) focus on high risk, high volume and problem-prone areas; (2) consider the incidence, prevalence and severity of identified problems; and (3) give priority to improvement activities that affect health outcomes, patient safety and quality of care. We expect an ASC would take immediate action to resolve any identified problems that directly or potentially threaten the care and safety of patients. . . .



D. Laboratory and Radiological Services

The conditions also include a new condition for laboratory radiological services. Regarding this condition, CMS stated:

In § 416.49, we would divide the current condition into two separate standards: Laboratory and radiologic services. In addition, we are proposing the expansion of the radiologic services requirement. The laboratory standard requirements would not change.

The proposed changes to the radiologic services standard would parallel the current laboratory standard by including requirements that the ASC would be required to meet, if applicable, when providing services directly or under arrangement.

The requirement at § 416.49(b)(1) is part of the current laboratory and radiologic services condition, and the language would remain unchanged. The proposed language at § 416.49(b)(2) would require the ASC to meet the requirements of the CfCs for portable x-ray suppliers found at § 486.100 through § 486.110 of this chapter if it is furnishing these services directly. We have also proposed that radiologic services furnished under arrangement would be performed by an entity that was certified by Medicare as a supplier of portable x-ray services by meeting the Medicare CfCs for portable x-ray services. This change would better ensure that high quality radiologic services are available to ASC patients.

E. Infection Control

With regard to a new condition for coverage for infection control, CMS stated:

We propose to establish a separate condition for infection control since control of infection is critically important to overall patient and staff health and safety.

We believe that surgery in an ASC must not entail a greater risk of infection to the patient than surgery in an inpatient setting. Medicare approved surgical procedures are performed in a variety of settings, and we believe that an effective infection control program should be present in all ASCs. One primary cause of infections is poor surgical technique and follow-up care. The Centers for Disease Control and Prevention (CDC) 1999 Guideline for Prevention of Surgical Site Infection [Infection Control and Hospital Epidemiology, Vol. 20 No. 4], also states that serious surgical infections can be explained by the emergence of antimicrobial-resistant pathogens and the increased numbers of surgical patients who are elderly. Furthermore, the CDC also reports that two million people are affected

by infections that annually occur in hospitals, and not including those health care-associated infections that occur in long-term care facilities, ambulatory-care facilities and outpatient settings

(CDC. Public health focus: surveillance, prevention and control of nosocomial infections (MMWR 1992; 41: 783–7)). A recent report on maximizing hand hygiene compliance and improved outcomes published in Infection Control Today reported that health care-associated infections subject patients to increased risk of morbidity and mortality, increased durations of care and increased health care treatment costs (E. Fendler and P. Groziak; Maximizing Hand-Hygiene Compliance to Improve Outcomes: A New Tool for Infection Control, Infection Control Today, November 2001). Furthermore the report by Fendler and Groziak, according to CDC estimates, states that implementing effective infection control programs prevents one-third of these infections.

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As noted by the former CMS Administrator Dr. Mark McClellan, during his testimony before the Senate Finance Committee May 18, 2006, “Medicare payments to ASCs are expected to better reflect the resources required to perform specific surgical procedures, and to be similar to payments under other payment systems. In its 2005 Report to Congress, CMS found that many orthopedic surgical specialty hospitals were more similar to ASCs than to acute care hospitals.” To address this problem, CMS is developing revisions to the payment rates and also the list of procedures eligible for payment. . . .

...

We are proposing this new condition as a method to capture specific patient care requirements in the pre-admission, pre-surgical, post-surgical and discharge phases of the ASC surgery process. The core objectives of this condition would be to ensure: (1) the patient can tolerate a surgical experience; (2) the patient’s anesthesia risk and recovery are properly evaluated; (3) the patient’s post-operative recovery is adequately evaluated; (4) the patient receives effective discharge planning; and (5) the patient is successfully discharged from the ASC.

Under the first proposed standard, “admission and pre-surgical assessment,” we would propose that each patient must have a comprehensive medical history and physical assessment completed not more than 30 days before the date of scheduled surgery by a physician (as defined in section 1861(r) of the Act), or other qualified practitioner in accordance with state law and ASC policy. We are proposing the 30-day time limit to remain consistent with our hospital conditions of participation that also requires a medical history and physical assessment be completed no more than 30 days before an elective procedure or admission. In addition, to ensure the ASC health care team would have all patient information available if needed, the ASC would be required to place the medical history and physical assessment in the patient’s medical record before the surgical procedure is started.

...

The proposed standard § 416.52(b), “post-surgical assessment” would require the ASC to ensure that a thorough assessment of the patient’s post-surgical condition is completed, documented in the medical record and that any post-surgical needs are addressed and included in the discharge notes. We propose to retain the current standard at § 416.42(a) that requires a physician to evaluate each patient for anesthesia recovery before discharge. The post-surgical assessment must be performed by a physician or other qualified practitioner in accordance with state law. The post-surgical assessment would assess all body systems and identify any unforeseen or unanticipated post-surgical medical issues. The goal would be to decrease the amount of post-surgical complications experienced after discharge in the home recovery setting.

Conclusion

Taken as a whole, these proposed rules would have a significant impact on ASCs from operational and business perspectives. CMS will accept public comments on the proposed rule through Oct. 30, 2007, and expects to publish a final rule later this year.

